

REMARKS

In the present communication, claim 9 has been amended; claims 12-26 and 29 have been canceled without prejudice or disclaimer; and no new claims have been added. The amendments add no new matter and are fully supported by the specification and claims as filed. As such, no new matter is introduced by the amendments. Applicants note that the withdrawn claims have been canceled to facilitate allowance. Upon entry of the present amendment, claims 1, 3, 5-9, 11 and 27-28 will be pending in this application.

Rejections under 35 U.S.C §112, first paragraph (enablement)

Applicants respectfully traverse the rejection of claims 9, 11-14 and 28 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement.

In determining whether the enablement requirement has been met, an analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. *See*, M.P.E.P. §2164.01 . Applicants assert that the enablement requirement is met, since one skilled in the art could clearly make and use the claimed invention based on the application as filed as well as the level of knowledge of one skilled in the art.

The Office Action indicates that the rejection is maintained against claims 9, 11 and 28, insofar as the claims recite “preventing heart failure”. Without acquiescing to the rationale presented in the Office Action, claim 11 has been amended to recite a “method of treating heart failure” as opposed to a “method of treating or preventing heart failure” thus rendering the rejection moot. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

The Office Action further indicates that the rejection is maintained against claims 12-14 for reciting methods requiring use of generic agents that modulate or upregulate sorcin expression. Without acquiescing to the rationale presented in the Office Action, claims 12-14

have been canceled rendering the rejection moot. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

Rejections under 35 U.S.C §102

Applicants respectfully traverse the rejection of claims 1, 3, 5 and 6 under 35 U.S.C. §102(a), as allegedly anticipated by Suarez et al. (*Am. J. Physiol. Heart Circ. Physiol.* 286(1):H68-75 (2004), Epub. Sept. 2003; hereinafter 'Suarez').

To anticipate, a single reference must inherently or expressly teach each and every element of the claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); and M.P.E.P. §2131.

Pursuant to M.P.E.P. §2132.01, an Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. §102(a). *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). Further, where the Applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by the filing of affidavit(s) establishing that the relevant portions of the publication originated with, or were obtained from, the Applicant. *Ex parte Hirschler*, 110 USPQ 384 (Bd. App. 1952).

Applicants submit herewith a declaration under 37 C.F.R. §1.132 by Dr. Wolfgang Dillmann establishing that the Suarez reference describes the inventors' own work, and further indicating that co-authors Thomas Dieterle, Patrick McDonough, Yun-Kyung Kim and Laurence Brunton of the Suarez reference are not inventors in the subject application. Accordingly, Suarez is no longer available as prior art under 35 U.S.C. §102, and consequently no longer available as prior art under 35 U.S.C. §103. *See* M.P.E.P. §2141.01. Since Suarez is no longer available as prior art against the instant application, reconsideration and withdrawal of this rejection are respectfully requested

Rejections under 35 U.S.C. §103

Applicants respectfully traverse the rejection of claims 1, 3, 5-9, 11 and 27-29 under 35 U.S.C. §103(a) as allegedly obvious over Suarez in view of Podsakoff et al. (U.S. Patent No. 6,335,011; hereinafter 'Podsakoff').

The U.S. Supreme Court decision in *KSR International v. Teleflex Inc.* modified the standard for establishing a *prima facie* case of obviousness. *KSR*, 550 US 398, 82 USPQ 2d 1385 (2007). Under the *KSR* rule, three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references still has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third, the prior art reference or combination has to teach or suggest all of the recited claim limitations. Factors such as the general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references.

The *2010 KSR Guidelines Update* provides additional guidance in view of decisions by the United States Court of Appeals for the Federal Circuit (Federal Circuit) since *KSR*. However, familiar lines of argument still apply, including teaching away from the claimed invention by the prior art, lack of a reasonable expectation of success, and unexpected results. Indeed, such arguments may have even taken on added importance in view of the recognition in *KSR* of a variety of possible rationales. *See* Federal Register, Vol. 75, No. 169, September 1, 2010, page 53645. Applicants respectfully submit that the Office has not met the burden of establishing a *prima facie* case of obviousness for the reasons discussed below.

As discussed above, Applicants submit herewith a declaration under 37 C.F.R. §1.132 by Dr. Wolfgang Dillmann establishing that the Suarez reference describes the inventors' own work. Accordingly, Suarez is no longer available as prior art under 35 U.S.C. §103. *See* M.P.E.P. §2141.01.

With regard to Podsakoff, the Office Action relies on Podsakoff as allegedly generally disclosing general gene therapy techniques that utilize adenoviral vectors as such treatments might apply to muscle tissue. Podsakoff generally relates to gene therapy techniques, however, Podsakoff fails to teach a method including administering an adenoviral or adeno-associated virus vector encoding sorcin to a subject to increase sorcin expression and contractile function as

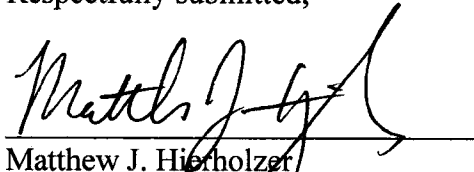
claimed. As such, Podsakoff fails to teach each and every element of the claimed invention. Since Saurez is not available as prior art and Podsakoff fails to disclose each and every limitation of the claimed invention, no *prima facie* case of obviousness may be established. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable consideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge \$405.00 as payment for the Request for Continued Examination fee to Deposit Account No. 07-1896. Additionally, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-referenced Attorney docket number.

Respectfully submitted,



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Date: February 14, 2011

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